

## **REMARKS**

Claims 33 and 35-46 are currently pending in the application. By this amendment, claim 32, previously withdrawn as drawn to a non-elected invention, is cancelled; claims 34 and 37 are cancelled; and claims 33, 35-36, 38-39, 41-42, and 43-46 are amended. The foregoing separate sheets marked as “Listing of Claims” shows all the claims in the application, with an indication of the current status of each.

### **Specification**

Examiner has objected to the specification because the first line of the first page of the specification does not reference related applications to which the present application claims priority. The specification has hereby been amended to recite that the present application claims benefit of United States patent application 09/059,573, now US patent 6,630,316, and United States patent application 08/928,392, now US patent 5,773,232, as required by Examiner.

In view of the forgoing, Applicant respectfully requests reconsideration and withdrawal of this objection.

### **Claims Objections**

Claim 46 is objected to due to the grammar in the phrase “wherein said control sample is liposomes containing ATP”.

Claims 46 has hereby been amended as follows: the word “is” has been replaced by the word “comprises”.

In view of the foregoing, Applicant respectfully requests withdrawal of this objection.

### **Claim Rejections**

#### **35 USC § 112, second paragraph**

Claims 33-47 stand rejected under 35 USC § 112, second paragraph, as indefinite.

Claims 34 and 47 have hereby been cancelled, thereby making moot this portion of the rejection.

Firstly, claim 33 has been amended to eliminate the repetition of the subject matter found in dependent claims 34, 36 and 37 (the clauses beginning with “wherein”), addressing Examiner’s observations concerning the inclusion of the “wherein” clauses. The subject matter of

claim 34 has been incorporated into claim 33 in a format that more clearly describes the method of the invention, and claim 34 has been cancelled. In addition, to provide additional clarity in the claim, the steps of the method have been assigned alphabetic or numeric indicators.

In addition, Claim 33 has hereby been amended to recite that activation of lymphocytes is determined by comparing the level of an intracellular component detected in the lymphocyte lysate with a level of the same component in a control sample: the lymphocytes are activated if the level in the lysate is greater than that of the control sample. This portion of the amendment clearly ties the result of the method to the preamble, thereby addressing Examiner's observations concerning the need for a correlation step.

Support for this amendment is found, for example, on page 19 at lines 5-7, where the use of controls is discussed. Support for the detection of an increase in an intracellular component is found, for example, on page 7 at lines 21-22, where detection of an intracellular component that increases as a result of activation is described.

Applicant submits that these amendments thus do not add any new matter, and respectfully requests withdrawal of this rejection and allowance of claim 33 and 35-46.

**Double Patenting:**

**Statutory: 35 USC § 101**

Examiner's point #5: Claim 47 stands rejected under 35 USC § 101 as claiming the same invention as that of claim 5 of prior US patent No. 6,630,316. Claim 47 is hereby cancelled, thereby making moot this rejection.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

**Nonstatutory**

Examiner's point #6: Claims 33-46 stand rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting over claims 1-6 of US patent 6,630,316. Examiner indicates that claims 33-46 would be allowable if a Terminal Disclaimer is filed.

Claim 34 has hereby been cancelled, thereby making moot this portion of the rejection.

Applicant herewith submits a Terminal Disclaimer that references US patent 6,630,316.

Examiner's point #7: Claims 33-47 stand rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting over claims 1-19 of US patent 5,773,232. Examiner indicates that claims 33-47 would be allowable if a Terminal Disclaimer is filed.

Claims 34 and 47 have hereby been cancelled, thereby making moot this portion of the rejection.

Applicant herewith submits a Terminal Disclaimer that references US patent 5,773,232.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

#### **Other matters**

**Amendment of claim 36:** Examiner states that the language of claim 33 is unclear due to the recitation of "derived from" and "transplanted organisms". Claim 33 has been amended to remove the entire section that contains this language. However, Applicant notes that the same recitations appear in claim 36. Claim 36 has now been amended to recite "from" rather than "derived from" as suggested by Examiner. Further, "transplanted organisms" has been replaced by "transplanted organs". Support for this latter amendment is found in the specification, for example, on page 11 at line 17, where "transplanted organs" are listed as a source of antigenic proteins.

Applicant submits that this amendment does not introduce any new matter, and respectfully request entry of the amendment and allowance of claim 36 in its present form.

**Amendment of claims 35, 36, 38, 39, 41, 42, 43 and 44:** Claim 34 has hereby been cancelled, its subject matter being included in claim 33. Claims which were previously dependent on claim 34 (35, 36, 38, 39, 41, 42, 43 and 44) have hereby been amended to depend from claim 33.

Applicant submits that these amendments do not introduce any new matter, being entirely formal in nature, and respectfully requests entry of the amendments, and allowance of claims 35, 36, 38, 39, 41, 42, 43 and 44.

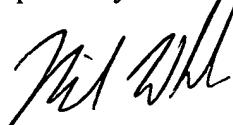
#### **Conclusion**

In view of the foregoing, it is requested that the application be reconsidered, that claims 33 and 35-46 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: ruth@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

If an extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



Michael E. Whitham  
Reg. No. 32,635

Whitham, Curtis, Christofferson & Cook, P.C.  
11491 Sunset Hills Road, Suite 340  
Reston, VA 20190  
703-787-9400  
703-787-7557 (fax)